

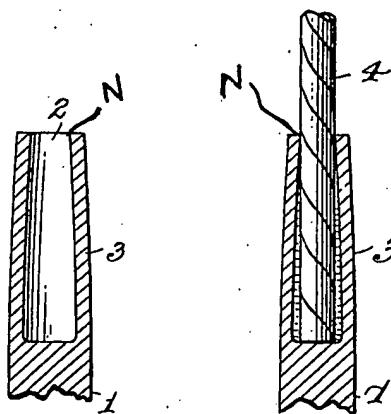
REMARKS

As a result of the foregoing amendments, Claims 1 and 10 have been amended, and new Claims 32-34 have been added. Accordingly, Claims 1-8 and 10-34 are pending in this application, with Claims 13 and 15-21 having been withdrawn from consideration.

Applicant's attorney thanks the Examiner for entering the request for continued examination filed on November 27, 2007 in connection with this application. Applicant's attorney also thanks the Examiner for withdrawing the finality of the previous Office Action.

In the present Office Action, independent Claim 1 has been rejected under 35 U.S.C. 103(a) based upon U.S. Patent No. 1,558,037 to Morton ("the Morton Patent"). With reference to the following reproductions of Figs. 2 and 3 thereof, which figures have been modified to include the reference letter N, the Morton Patent discloses a surgical needle (1) that includes a longitudinal recess (2) having a diameter that is only "a trifle larger than the diameter of the suture." The neck (N) of the recess (2) is constricted (as by spinning or swaging) so that it is "only slightly greater than the diameter of the suture (4)" (see page 2, lines 19-32). A **small amount** of adhesive may then be placed in the recess (2) so as to anchor the suture (4) therein. The needle (1) is also described as "not ... unduly large, **but of only slightly greater diameter than the suture**" (see page 2, lines 46-48).

Fig. 2. *Fig. 3.*



Because the neck (N) of the recess (2) is constricted, the adhesive placed therein will only occupy an interior portion of the recess (2). More particularly, the adhesive extends from the closed end of the recess (2) to a point intermediate the closed end and the neck (N). In other words, the structure and size of the recess (2) (including its constricted neck (N)) and the close fit of the suture (4) therein would prevent the adhesive from extending from the bottom of the recess (2) all the way to its neck (N). Since there is no adhesive at the neck (N) of the recess (2), it follows then that the adhesive can not surround the suture (4) at the neck (N).

In contrast to the recess of the Morton Patent needle, the diameter of the suture hole of the present application (i.e., the diameter at the first end of the needle) is significantly larger than the diameter of the suture. According to the present application, “the larger the suture hole, the greater the potential surface area to which [an] adhesive in accordance with the present invention may bond. Furthermore, the use of adhesives permits a larger suture hole, which can accommodate a **range of suture sizes** therein.” Because the diameter of the suture hole is significantly larger than the diameter of the suture, it is easier to insert the suture into the suture hole (see Figs. 3, 4, 5d and 5e). This relative sizing of the suture hole diameter and the suture diameter results in an advantageously reduced “hole centering” requirement, which is described as “particularly important in an automated process” (see page 1, paragraphs 0011 and 0013 of the publication of the present application).

The Examples of the present application illustrate the foregoing features, including suture hole diameters (i.e., the diameter at the first end of the needle) that are significantly larger than the diameters of the sutures inserted therein. For the Examiner’s reference in the following discussion of needle hole and suture sizes, attached as Exhibit A is a chart of U.S.P. suture sizes and their respective diameter sizes, as listed on a reference web site (<http://en.wikipedia.org/wiki/Suture>). As indicated in the chart, absorbable sutures (e.g.,

Vicryl sutures, as discussed in Examples 1-5 and 7) and non-absorbable sutures (e.g., Ethilon sutures, as discussed in Example 1, and ProNova sutures, as discussed in Example 5) of the same U.S.P. size designation have the same diameters.

All of the Examples, taken together, define a broad range of first needle hole diameter-to-suture diameter ratios. More particularly, the needle hole diameter is larger than the suture diameter by at least 26.8%, and by as much as 78.9%. To facilitate consideration and discussion, the sizes of the needle holes and sutures disclosed in all of the Examples are presented in the table below, along with the calculations of the respective size differences.

Example #	Needle Hole Diameter (mm, converted from mil (one mil being one thousandth of an inch and equal to 0.0254 mm))	Suture Size and Diameter (mm)	Difference in Diameter Lengths (mm)	Percentage Difference
1	0.37	3-0 - 0.20	0.17	42.5%
	0.40		0.20	50%
2	0.63	4-0 - 0.15 2-0 - 0.30 1 - 0.40	0.48	76.2%
			0.33	52.4%
			0.23	36.5%
3	0.63	1 - 0.40	0.23	36.5%
4	0.63	3-0 - 0.20	0.43	68.3%
5	0.41	2-0 - 0.30	0.11	26.8%
	0.43		0.13	30.2%
	0.46		0.16	34.8%
	0.51		0.21	41.2%
6	0.19	5-0 - 0.10 6-0 - 0.07 7-0 - 0.05 8-0 - 0.04	0.09	47.4%
			0.12	63.2%
			0.14	73.7%
			0.15	78.9%
7	0.63	4-0 - 0.15	0.48	76.2%

By the foregoing amendments, independent Claim 1 has been amended to recite a third diameter (i.e., the diameter of the suture end inserted into the needle hole) and to clarify that the first hole diameter of the needle hole is greater than the third diameter by a factor that

allows the hole to accommodate the insertion of a range of differently-sized sutures therein. Claim 1 has also been amended to recite that the adhesive extends from the first end of the needle to the bottom wall of the hole, and substantially surrounds the end of the suture within the hole.

Applicant's attorney respectfully submits that the close fit of the Morton Patent suture (4) within the needle recess (2) (see Fig. 3 above) actually **teaches away** from amended independent Claim 1. The Morton Patent needle (1) is **not** suited to accommodate the insertion of a range of differently-sized sutures, and does not permit placement of the adhesive at the neck (N) of the recess (2) such that it surrounds the end of the suture (4). Thus, there are both structural differences and functional differences between the armed suture of amended Claim 1 and the Morton Patent needle. It is therefore further respectfully submitted that all of the prior art rejections of Claim 1 based on the Morton Patent have now been overcome.

In view of the foregoing arguments, applicant's attorney respectfully submits that amended independent Claim 1 is directed to patentable subject matter and, in the absence of any other rejections, such claim should be in condition for allowance. Because Claims 2-8, 10-12, 14, and 22-31, also depend from amended independent Claim 1, they are also believed to be in condition for allowance for the same reasons that Claim 1 is allowable. In other words, it is respectfully submitted that all of the prior art rejections of Claims 2-8, 10-12, 14, and 22-31 have now been overcome.

With reference to new Claims 32-34, they each depend from amended Claim 1, and recite that the first needle hole diameter is greater than the third (suture end) diameter by at least 26.8% (Claim 32), by not more than 78.9% (Claim 33), and by a range of between 26.8% and 78.9% (Claim 34), respectively. These percentage differences were derived from Examples 5 and 6 of the present application (see chart with calculations above), and they represent the

smallest and greatest size differences between the suture diameter and the needle hole diameter in all of the Examples.

In view of the foregoing amendments and remarks, applicant and his attorney respectfully request the reexamination and allowance of Claims 1-8, 10-12, 14, and 22-31, and the examination and allowance of new Claims 32-34. If, however, such action cannot be taken, the Examiner is cordially invited to place a telephone call to applicant's attorney in order that any outstanding issue may be resolved without the issuance of another Office Action.

The accompanying two-month Extension Petition authorizes the Examiner to charge the associated extension fee (\$460) to Deposit Account No. 501561. If there are any additional fees due as a result of this Amendment, including extension and petition fees, the Examiner is hereby authorized to charge them to Deposit Account No. 501561.

Respectfully Submitted,

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EXHIBIT A

SUTURE SIZE CHART

U.S.P. Designation	Diameter (mm) of synthetic absorbable and non- absorbable sutures
10-0	0.02
9-0	0.03
8-0	0.04
7-0	0.05
6-0	0.07
5-0	0.10
4-0	0.15
3-0	0.20
2-0	0.30
0	0.35
1	0.40

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In view of the foregoing amendments and remarks, applicant and his attorney respectfully request the reexamination and allowance of Claims 1-8, 10-12, 14, and 22-31, and the examination and allowance of new Claims 32-34. If, however, such action cannot be taken, the Examiner is cordially invited to place a telephone call to applicant's attorney in order that any outstanding issue may be resolved without the issuance of another Office Action.

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